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EXAMINER	
GARVEY, TARA L	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,371	KATZ ET AL.	
	Examiner	Art Unit	
	Tara L. Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13,36-65,73,74,77-79 and 132-168* is/are pending in the application.

4a) Of the above claim(s) *1, 3-13,36-38,49-56 and 58-65,73,74,77-79, 132-159 and 163-168* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-48,57 and 160-162* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/04,6/05,7/05*, 6/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims1, 3-13,36-65,73,74,77-79 and 132-168 are pending. Claims 1, 3-13, 36-38, 49-56, 58-65, 73, 74, 77-79, 132-159 and 163-168 have been withdrawn. Claims 2, 14-35, 66-72, 75-76, 80-131 have been cancelled.

Election/Restrictions

Claims 1, 3-13,36-38,49-56 and 58-65,73,74,77-79 and 132-168 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 5, 2005.

Applicant's election with traverse of Group III (claims 39-48, 57 and 160-162) in the reply filed on May 5, 2005 is acknowledged. The traversal is on the ground(s) that an undue search burden does not exist. This is not found persuasive because the inventions are distinct and a search burden exists. While searches may partially overlap, they also extend beyond one another. In, for example, the case of a product and a process of using that product, a reference may exist that teaches the product of Group I drawn to adipose-derived stem cells and implants, but does not teach the same method of using this product as claimed in Group III, which is drawn to a method of differentiating a cell.

The requirement is still deemed proper and is therefore made FINAL.

Claim 40 was restricted to examination of differentiating the cells in a neurogenic medium and therefore claims 41-46 would not read on the elected invention. However, claims 41-46 have been rejoined and examined in the following office action.

Priority

Claims 39-48 and 57 are granted a filing date of March 9, 2004 since reference to the priority applications does not appear in the first paragraph of the specification. Once the claim to priority applications appear in the specification, claim 160 is granted priority to March 10, 1999 and claims 39-48, 57, 161 and 162 will be granted priority to PCT/US00/06232 with a filing date of March 10, 2000. The provisional applications 60/123,711 and 60/162,462 do not disclose that the adipose derived stem cells of the invention have the ability to differentiate into a nerve cell or that the cells can be grown in conditioned media or in co-culture with another cell.

If applicant desires benefit of a previously filed application under 35 U.S.C. 120 and 119 (e), specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing

date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional

information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-42, 44-45, 47 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuk et al (Molecular Biology of the Cell, December 2002, volume 13, pages 4279-4295 as referenced on the IDS of June 24, 2005).

Claims 39-42, 44-45, 47 and 57 are drawn to a method of differentiating an isolated adipose-derived stem cell that is multipotent in that it has the capacity to differentiate into a nerve cell and a fat cell, a bone cell, a cartilage cell or a muscle cell by culturing the cell in morphogenic medium.

Zuk et al teach differentiation in vitro of processed lipoaspirate (PLA) cells obtained from adipose tissue into neuronal cells, bone cells, fat cells, cartilage cells and muscle cells using neurogenic medium, osteogenic medium, adipogenic medium,

chondrogenic medium and myogenic medium and then analyzing the cells for specific physical characteristics, markers or activities that identify the cell as having differentiated into a certain lineage (abstract, pages 4280-4281, page 4283, page 4288, right column, paragraphs 2-3 bridging page 4290, page 4290, left column, paragraph 1 and right column, paragraphs 1-2 and page 4291. Thus, Zuk et al teach all that is recited in the instant claims.

Claims 39, 40, 43, 47, 48 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilkison et al (US 2001/0033834).

Claims 39, 40, 43, 47, 48 and 57 are drawn to a method of differentiating a multipotent adipose derived stem cell in morphogenic media, especially neurogenic, either *in vitro* or *in vivo*.

Wilkison et al teach an isolated multipotent adipose derived stromal stem cell that has been differentiated into a neuronal cell by culturing the cell in a medium that induces differentiation into a neuronal lineage and then characterizing the cell for neuronal specific markers such as NeuN, NF-M, NSE, nestin and trkA. The cells can be cultured either *in vivo* or *in vitro*. The adipose-derived stem cell can be grown in a media with embryonic extract and fetal serum, can be dedifferentiated and monitored for loss of adipose stem cell markers, which reads on an embryonic or fetal morphogenesis (page 3, right column, paragraphs 1-4, page 4, left column, paragraphs 2-3 and right column, paragraphs 2, 3 and 5, page 5, left column, paragraph 4 and right column, last paragraph bridging page 6, left column, paragraphs 1 and 2, pages 8-9, Examples 2

and 3). The adipose derived stromal cell disclosed in the method of differentiation reads on multipotent stem cell that differentiates into nerve and inherently an adipose or fat cell since it was derived from adipose tissue. Soda et al describes a stem cell derived from adipose tissue that is capable of differentiating into an adipocyte (Soda et al. International Journal of Cell Cloning, 1983, volume 1, pages 79-84, especially page 79, paragraph 1; as referenced in the IDS submitted June 24, 2005).

Claim 160 is rejected under 35 U.S.C. 102(b) as being anticipated by Ailhaud et al (Diabete and Metabolisme (1983) volume 9, pages 125-133; as referenced in the IDS submitted on June 24, 2005).

Claim 160 is drawn to a method of differentiating an adipose derived stem cell in a suitable medium.

Ailhaud et al teach differentiation of stem cells from adipose tissue into adipocytes using a medium containing adipogenic factors (page 125, paragraph 1, page 126, left column first full paragraph, lines 1-5). Thus, Ailhaud et al teach all that is recited in the instant claim

Claim 162 is rejected under 35 U.S.C. 102(e) as being anticipated by Gimble et al (US 6,555,374).

Claim 162 is drawn to a method of inducing the differentiation of an isolated adipose-derived stem cell by co-culturing the cell with a desired cell type.

Gimble et al teach a method of differentiating an adipose derived stromal cell into a hematopoietic supporting stromal cell by co-culture with hematopoietic cells (column 6, lines 3-16, column 7, lines 59-61, columns 14-17, Examples 2-5). Thus, Gimble et al teach all that is recited in the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39-48 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilkison et al (US 2001/0033834) in view of Halvorsen et al (US 6,429,013), Halvorsen et al (US 2002/0119126) and Gimble (US 6,555,374).

Claims 39-48 and 57 are drawn to a method of differentiating a multipotent adipose derived stem cell in neurogenic, adipogenic, chondrogenic, myogenic, osteogenic or stromal media, monitoring the cell for the particular differentiation and the differentiation can occur either *in vitro* or *in vivo*.

Wilkison et al has been described previously.

Wilkison et al do not teach culturing the adipose derived stem cell in adipogenic, chondrogenic, myogenic, osteogenic or stromal media and monitoring the cell for these particular differentiation characteristics.

Halvorsen et al (US 6,429,013) teach a method of differentiating adipose-derived stromal cells in a chondorgenic medium and then assaying the cell for characteristics of a chondrocyte (abstract, column 2 lines 24-47, column 3, lines 55-67 bridging column 4, lines 1-67, columns 5-6 and columns 8-9, Example 1).

Halvorsen et al (US 2002/0119126) teach a method of differentiating adipose-derived stromal cells using an osteogenic or adipogenic medium and then analyzing the cells for osteoblast properties or adipocyte properties (abstract, page 2, right column, page 3, page 4, right column, third full paragraph and pages 5-6, Example 2).

Gimble et al teach a method of differentiating adipose-derived stromal cells in a myogenic or stromal medium and then analyzing the cells for properties associated with either myocytes or stromal cells (abstract, column 2 lines 55-67 bridging column 3 lines 1-19, column 5 lines 21-27, 66-67 bridging column 6 lines 1-67, column 7, column 8, column 9 lines 63-67 bridging column 10 lines 1-52 and columns 13-19, Examples 1-6 and 7).

It would have been obvious to one or ordinary skill in the art to modify the teachings of Wilkison et al to differentiate a multipotent adipose-derived stem cell that is capable of becoming a nerve cell and a fat, bone, cartilage or muscle cell using adipogenic, chondrogenic, myogenic, osteogenic or stromal medias and monitoring the cell for these properties because Wilkison et al teach the differentiation of such a multipotent adipose derived stem cell using neurogenic media and analyzing the cell for properties of a neuronal cell and because Halvorsen et al and Gimble et al teach that adipose derived stem cells can be differentiated into these lineages using adipogenic, chondrogenic, myogenic, osteogenic or stromal medias.

One would have been motivated to do so in order to receive the expected benefit, as suggested by Wilkison et al and actually exemplified by Halvorsen et al and Gimble et al, of differentiating an adipose-derived stem cell into a fat, bone, cartilage, muscle or stromal cell for use in cell therapies. Absent of any evidence to the contrary, there would have been reasonable expectation of success in using these particular medias to differentiate adipose derived stem cells into a particular lineage since these medias have been shown previously to differentiate adipose-derived stem cells as well as other stem cells into these cell lineages.

Claims 160-161 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ailhaud et al (Diabete and Metabolisme (1983) volume 9, pages 125-133; as referenced in the IDS submitted on June 24, 2005) in view of Golde et al (US 4,438, 032).

Claims 160-161 are drawn to a method of inducing the differentiation of an isolated adipose-derived stem cell using a conditioned medium of a specific cell type.

Ailhaud et al teach differentiation of stem cells from adipose tissue into adipocytes using a medium containing adipogenic factors (page 125, paragraph 1, page 126, left column first full paragraph, lines 1-5).

Ailhaud et al do not teach using a conditioned medium of a specific cell type for the differentiation.

Golde et al teach culturing stem cells in a conditioned medium to differentiate the cells into a desired cell type (column 6, lines 45-56).

It would have been obvious to one or ordinary skill in the art to modify the teachings of Ailhaud et al to differentiate the cells in a conditioned medium because Ailhaud et al teach that adipose-derived stem cells can be differentiated and Golde et al demonstrate that stem cells can be differentiated into a particular cell type using a conditioned medium.

One would have been motivated to do so in order to receive the expected benefit, as suggested by Ailhaud et al and actually exemplified by Golde et al, of differentiating adipose-derived stem cells in a conditioned medium.

Absent of any evidence to the contrary, there would have been reasonable expectation of success in differentiating adipose-derived stem cells in conditioned medium since other stem cells have been differentiated successfully using conditioned medium.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claim 39 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for differentiation of adipose-derived stem cells in some morphogenic medium such as adipogenic, osteogenic, chondrogenic, myogenic and embryonic, does not reasonably provide enablement for differentiation of adipose-derived stem cells into any cell type in any morphogenic medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art, relative skill in the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claim, with the most relevant discussed below.

Nature of the invention: The claim is drawn to a method of differentiating an isolated adipose-derived stem cell using any morphogenic media under conditions that will allow the cell to differentiate. The isolated cell is multipotent in that it can differentiate into a nerve cell and a fat, bone, cartilage or muscle cell.

Breadth of the claim: The claim is broad in that it is drawn to a method in which the adipose-derived stem cell can differentiate into any cell type using any morphogenic medium.

Guidance in the specification/Existence of a working example: The specification describes differentiation of adipose-derived stem cells using adipogenic, osteogenic, myogenic, chondrogenic and embryonic medias where the working examples provide the composition of these medias. The specification does not describe how to culture the adipose-derived stem cells into any cell using any morphogenic media.

State of the art/Predictability of the art: At the time of the applicants' invention, the art describes differentiating adipose-derived stem cell using adipogenic, osteogenic, chondrogenic myogenic, neurogenic and stromal medias (Wilkison et al (US 2001/0033834; see page 3, right column, paragraphs 1-4, page 4, left column, paragraphs 2-3 and right column, paragraphs 2, 3 and 5, page 5, left column, paragraph 4 and right column, last paragraph bridging page 6, left column, paragraphs 1 and 2, pages 8-9, Examples 2 and 3; Halvorsen et al (US 6,429,013) see abstract, column 2 lines 24-47, column 3, lines 55-67 bridging column 4, lines 1-67, columns 5-6 and columns 8-9, Example 1; Halvorsen et al (US 2002/0119126) see abstract, page 2, right column, page 3, page 4, right column, third full paragraph and pages 5-6, Example 2;

Gimble et al (US 6,555,374) see abstract, column 2 lines 55-67 bridging column 3 lines 1-19, column 5 lines 21-27, 66-67 bridging column 6 lines 1-67, column 7, column 8, column 9 lines 63-67 bridging column 10 lines 1-52 and columns 13-19, Examples 1-6 and 7). The art has not described differentiation of adipose-derived stem cells into any cell type using any morphogenic medium. Therefore, experimentation to determine all the cell types that adipose-derived stem cells could potentially differentiate towards using a specified morphogenic medium would require a large amount of trial and error experimentation.

Quantity of experimentation: In determining all the cell types that adipose-derived cells could be differentiated into using a morphogenic medium, the adipose-derived stem cells would need to cultured in all type of medias and then the cells would need to be analyzed for certain characteristics of a particular cell type to determine if the medium was effective. The analysis of all types of medias would require extensive experimentation.

Conclusion: In view of the unpredictable nature of the art and the enormous amount of experimentation needed to analyze the effect of all morphogenic medias on the differentiation of the adipose-derived stem cells, the experimentation would have been undue. Thus, it would require undue and unpredictable experimentation for one of skil in the art to make the claimed invention. Therefore, the claimed invention of differentiation of adipose-derived stem cells into any cell type using any morphogenic media is not considered to be fully enabled by the instant specification.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 160-162 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 35-37 of copending Application Numbers 10/845,315 and 10/740,315. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
Art Unit 1636

TLG

JAMES KETTER
PRIMARY EXAMINER